

## REMARKS

Reconsideration of the application is respectfully requested.

### REJECTION UNDER 35 U.S.C. 102(b)

Claims 27-32, 34, 36, 37, 40, 42, 43, 45, 47 and 49 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,382,261 to Palmaz.

#### Claims 27-32, 34, 36, 37, and 40

Palmaz fails to disclose or suggest the step of inserting a blocking element in a bronchial passageway of the individual, as recited in independent claim 27. Palmaz makes no mention whatsoever of a bronchial passageway. Palmaz relates to a vessel occluder that provides permanent occlusion of a blood vessel, not a bronchial passageway. For example, according to Palmaz the deployed device operates in an environment defined by blood pressure caused by systolic contraction. (Palmaz, col. 6, lines 39-40.) Accordingly, Palmaz fails to teach each and every element of claim 27 as it fails to make any mention or suggestion of inserting a blocking element in a bronchial passageway.

The examiner argued in the office action that Palmaz discloses a blocking element in a lung passageway since Palmaz mentions pulmonary arteriovenous fistula as an example of when permanent occlusion of a vessel might be desirable. However, pulmonary arteriovenous fistula does not relate to bronchial passageway. Rather, pulmonary arteriovenous fistula is a condition in which an abnormal connection (fistula) develops between an artery and vein in the lungs. Thus, Palmaz mentions pulmonary arteriovenous fistula in the context of treating a blood vessel, such as an artery or a vein. Palmaz makes no mention of using a vessel occluder in the treatment

of a disease that would affect a bronchial passageway. Palmaz provides no need or suggestion of inserting a blocking element in a bronchial passageway.

Although Palmaz states that the vessel occluder is for "occlusion of a vessel in a person", Palmaz never describes or even suggests that the vessel could be used in a bronchial passageway. Rather, Palmaz mentions specific instances of use only in a blood vessel, including therapeutic occlusion, or embolization, of the renal artery; occlusion of a Blalock-Taussig Shunt; and pulmonary arteriovenous fistulae and transjugular intrahepatic stent shunt occlusion. (Palmaz, col. 1, lines 17-20.) Palmaz does mention non-vascular applications such as therapeutic ureteric occlusion and the occlusion of vessels feeding large cancerous tumors. (Palmaz, col. 1, lines 20-23.) However, Palmaz makes no mention or suggestion whatsoever of applications that would include inserting the blocking element in a bronchial passageway of an individual, as recited in independent claim 27.

In view of the foregoing, the examiner should withdraw the rejection of claim 27 under 35 U.S.C. 102(b) as Palmaz fails to teach each and every element of claim 27. Claims 28-32, 34, 36, 37, and 40 are patentable based on their dependence on claim 27 as well as on their own merit.

Claims 42, 43, 45, and 47

Palmaz also fails to disclose or suggest a securing element comprising a self-expanding stent that engages a wall of the bronchial passageway to secure the apparatus therein, wherein the securing element maintains the apparatus in a fixed position in the bronchial passageway without migration. Palmaz makes no mention of a self-expanding stent. Rather, Palmaz discloses a stent

that is expanded using a balloon catheter wherein a balloon is positioned inside the stent and expanded. (See, e.g., column 5, lines 38-43.)

Stents that are expanded via a balloon catheter are not suited for placement in a bronchial passageway. Such stents tend to deform and collapse in the bronchial passageway such as during coughing. As a result, stents of the type disclosed in Palmaz do not maintain a fixed position in the bronchial passageway but rather undesirably migrate in the bronchial passageway. Applicant provides herein as Exhibit 1 an article entitled "Deformation and Migration of Palmaz Stents after Placement in the Tracheobronchial Tree" (Perini et al., 1999). In the article, Perini discloses that the Palmaz stent collapses and migrates when placed in a bronchial passageway. Applicant submits that the Palmaz stent is unsuited for placement in a bronchial passageway because the stent does not maintain the apparatus in a fixed position in the bronchial passageway without migration.

Palmaz fails also to disclose or suggest a blocking element that prevents air from flowing past the apparatus in an inhalation direction and also prohibits air from flowing past the apparatus in an exhalation direction, as recited in claim 42. As discussed above, Palmaz discloses an occluder that occludes blood vessels. The occluder is not adapted to prohibit air flow past the apparatus but is rather adapted to prohibit blood flow past the apparatus.

In view of the foregoing, the examiner should withdraw the rejection of claim 42 under 35 U.S.C. 102(b) as Palmaz fails to teach each and every element of claim 42. Claims 43, 45, and 47 are patentable based on their dependence on claim 42 as well as on their own merit.

Claim 49

Palmaz fails to disclose or suggest inserting a material in a bronchial passageway of the individual so that the material prohibits air from flowing through the bronchial passageway in an inhalation direction and also prohibits air from flowing through the bronchial passageway in an exhalation direction, as recited in claim 49. As discussed above with reference to claim 27, Palmaz makes no mention whatsoever of inserting anything into a bronchial passageway. The examiner should withdraw the rejection of claim 49.

REJECTION UNDER 35 U.S.C. 103

Claims 33, 35, 38, 39, 41, and 48 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz in view of various references. The examiner did not provide any specific basis for the rejection of claims 44 and 46. Applicant assumes that claims 44 and 46 are rejected on the same basis as similar claims 33 and 35. As discussed above, Palmaz fails to disclose or suggest all of the elements of independent claims 27 and 42 from which claims 33, 35, 38, 39, 41, 44, 46, and 48 depend. The secondary references cited by the examiner fail to disclose or suggest the missing elements. Thus, claims 33, 35, 38, 39, 41, 48 are patentable over the cited art based on their dependence on either claims 27 or 42.

In addition, claims 33, 35, 38, 39, 41, 48 are patentable on their own merit as they recite features that are not taught or suggested by Palmaz or the other cited references. For example, claim 41 recites that the method is for treating an individual having emphysema. The examiner acknowledged that Palmaz does not disclose using the occluding device to treat emphysema. The examiner argued that it would be obvious to use the device of Palmaz to treat emphysema by

using the device to occlude the left mainstream bronchus rather than the device used by Auerbach.

However, there would be no motivation to use the device of Palmaz in place of the device used by Auerbach to treat emphysema. The Palmaz device is a device that provides permanent occlusion of a vessel. The device and method of Auerbach are directed toward treatment of pulmonary interstitial emphysema (PIE), which is an iatrogenic pulmonary condition of a premature infant with immature lung. Auerbach teaches that a balloon catheter can be temporarily inserted into an infant's lung "to facilitate weaning from ventilatory support while avoiding endobronchial trauma from selective intubation or the need for resection of lung parenchyma." (Auerbach, page 57, first full paragraph.) There would be no motivation to use the permanent occlusion device of Palmaz in the Auerbach procedure that calls for temporary occlusion of a bronchial passageway. To the contrary, Auerbach describes treatment of a premature infant. A person of ordinary skill would be motivated against permanently occluding the bronchial passageway of an infant. Auerbach thus teaches away from combining its procedure with the permanent occlusion device of Palmaz.

In addition, Palmaz discloses that the vessel occluder is completely released in a body vessel, which would render the Palmaz device unsuitable for use in the procedure disclosed by Auerbach. In Auerbach, the occlusion member is a balloon that is permanently attached to a catheter. As discussed in Auerbach, the use of a balloon attached to a catheter permits selective inflation and deflation of the balloon via the catheter during treatment and also permits repositioning of the balloon via the catheter should the balloon become misplaced. If the Palmaz device were used in the Auerbach procedure, it would be impossible to selectively reposition the

device or selectively re-occlude the device should it become detached as the Palmaz device specifically designed for complete release in the body vessel. The Auerbach procedure requires the ability to selectively reposition and re-inflate the bronchial passageway. Thus, the Palmaz device would be completely unsuited for use in the Auerbach procedure.

In view of the foregoing, the rejections under 35 U.S.C. 103 should be withdrawn.

### CONCLUSION

It is believed that all of the pending claims have been addressed in this paper. However, failure to address specific rejection, issue, or comment, does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above are not intended to be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

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Page : 12 of 12

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Applicant respectfully submits that the claims are in condition for allowance, and a notice to that effect is respectfully solicited. If the Examiner has any questions regarding this response, the Examiner is invited to telephone the undersigned at (858) 314-1518.

Respectfully submitted,

  
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